PATENT COOPERATION TREATY **PCT**

| RE | C'D | Î | î | APR | 2006 |
|----|-----|---|---|-----|------|
| W | IPO | | | | PCT |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference AY/2004.1628 | FOR FURTHER AC | CTION S | See Form PCT/IPEA/416 | | |
|---|---|-------------------------|---|--|--|
| International application No. PCT/SG2004/000417 | International filing da 17 December 2004 | te (day/month/year) | Priority date (day/month/year) 19 December 2003 | | |
| International Patent Classification (IPC) or national classification and IPC | | | | | |
| Int. Cl. | | | | | |
| ACTION DATE: 28 March | | G0114 33/00 (2000.01 | , | | |
| Applicant | | _ | | | |
| AGENCY FOR SCIENCE, TEC | HNOLOGY AND RE | ESEARCH et al | | | |
| | · · · · · · · · · · · · · · · · · · · | | | | |
| 1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. | | | | | |
| 2. This REPORT consists of a total of 4 | sheets, including this o | over sheet. | | | |
| 3. This report is also accompanied by ANI | NEXES, comprising: | | • | | |
| a. (sent to the applicant and to the | e International Bureau) | a total of sheets, as f | ollows: | | |
| sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). | | | | | |
| sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental | | | | | |
| Box. b. (sent to the International Bured | an only) a total of (indic | eate type and number of | electronic carrier(s)) , containing | | |
| a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to | | | | | |
| Sequence Listing (see Section 802 of the Administrative Instructions). 4. This report contains indications relating to the following items: | | | | | |
| | Basis of the report | | | | |
| Box No. II Priority | | | | | |
| Box No. III Non-establishme | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | |
| Box No. IV Lack of unity of | Lack of unity of invention | | | | |
| | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | |
| Box No. VI Certain documen | • • • | | | | |
| Box No. VII Certain defects in | Box No. VII Certain defects in the international application | | | | |
| X Box No. VIII Certain observations on the international application | | | | | |
| Date of submission of the demand Date of completion of this report | | | | | |
| 18 October 2005 | | 28 March 2006 | | | |
| Name and mailing address of the IPEA/AU | | Authorized Officer | | | |
| AUSTRALIAN PATENT OFFICE | T T A | P. | Of the second | | |
| PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au | | O.L. CHAI | | | |
| Facsimile No. (02) 6285 3929 Telephone No. (02) 6283 | | | | | |
| • | | | | | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000417 · ·

| Box | No. I | Basis of t | he report | | | |
|-----|--------|--|--------------------------------|--|---|--|
| 1. | With | regard to the lang | guage, this | report is based on: | | |
| | X | The international | application | in the language in which it was | filed | |
| | | A translation of translation furnis | | onal application into purposes of: | | , which is the language of a |
| | | internation | nal search (u | ander Rules 12.3(a) and 23.1 (b) |) | |
| | | publication | n of the inte | rnational application (under Rul | e 12.4(a)) | |
| | | <u></u> | _ | ary examination (Rules 55.2(a) | | |
| 2. | furni | ished to the receiv " and are not ann | ving Office is exed to this | = - | eport is based on (replaceme r Article 14 are referred to it | ent sheets which have been n this report as "originally |
| | X | the international | application | as originally filed/furnished | | , |
| | \Box | the description: | | | | t |
| | L | | pages | as originally filed/furnished | | |
| | | | pages* | received by this Authority on | with the letter of | |
| | _ | | pages* | received by this Authority on | with the letter of | • |
| | | the claims: | | | | • |
| | | • | pages | as originally filed/furnished | | |
| | | | pages* | as amended (together with any | | |
| | | | pages* | received by this Authority on | with the letter of | t |
| | | 4. 1. | pages* | received by this Authority on | with the letter of | |
| | | the drawings: | | | | |
| | | | pages | as originally filed/furnished | with the letter of | |
| | | | pages* pages* | received by this Authority on received by this Authority on | with the letter of with the letter of | |
| | | a sequence listing | | related table(s) - see Supplement | | ce Listing. |
| 3. | | _ | • | ted in the cancellation of: | , | |
| | لــا | | | | | |
| | | | cription, pag | , | | |
| | | <u></u> | ms, Nos. | · - | | |
| | | | wings, sheet | • | | |
| | | the sequ | ience listing | (specify): | | |
| | | | | to the sequence listing (specify) | | |
| 4. | | This report has b made, since they 70.2(c)). | een establis have been | thed as if (some of) the amendm considered to go beyond the dis | ents annexed to this report a closure as filed, as indicated | nd listed below had not been in the Supplemental Box (Rule |
| | | the desc | cription, pag | es | | |
| | | | ms, Nos. | | • | |
| | | | wings, sheet | s/figs | | |
| | | <u></u> | uence listing | _ | | |
| | | <u> </u> | | | | ŧ |
| | | any tabl | le(s) related | to the sequence listing (specify) | : | |
| * | If i | tem 4 applies, some | or all of thos | se sheets may be marked "supersed | ed." | • |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000417

| | Reasoned statement un citations and explanation | | le 35(2) with regard to novelty, inventive orting such statement | e step or industrial applicability; |
|--------------|---|--------|--|-------------------------------------|
| 1. Statement | | | | |
| Nove | lty (N) | Claims | 1-49 | YES |
| • | | Claims | | NO |
| Inven | tive step (IS) | Claims | 4-14, 16, 18-19, 32-44 | YES |
| | | Claims | 1-3, 15, 17, 20-31, 45-49 | NO . |
| Indus | trial applicability (IA) | Claims | 1-49 | YES |
| | | Claims | | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 Protein Expression and Purification 24, pp 282-291 (2002)
- D2 J Biological Chem 268, pp 1479-1487 (1993)
- D3 Avian Diseases 47, pp 1486-1490 (Oct 2003)
- D4 J Biological Chem 275, pp 18965-18994 (2000)
- D5 J Biological Chem. 276, pp 9910-9916 (2001)
- D6 Applied and Environmental Microbiology 68, pp 1817-1826 (2002)
- D7 WO 2002/083725
- D8 WO 2003/048783

Novelty (N)

The present invention relates to a device for the separation of proteins, particularly a protein separation device comprising a chaperone protein immobilised on a substrate. The proteins include common heat shock proteins (hsp) such as hsp 60 (also referred to as GroEL).

None of the cited documents disclose all of the features of each of the independent claims. Therefore all of the claims are novel with regards to Article 33(2) of the PCT.

Inventive Step (IS)

D2 discloses immobilised Hsp90 on a Affi-Gel beads column retained certain proteins and these proteins can be isolated and identified. Given this citation, a person skilled in the art would be led directly to use this information for separation of associated proteins. Therefore, claims 1-3, 15, 17, 20-31, 45-49 are not inventive with regards to Article 33(3) of the PCT.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000417

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- 1. Claim 1 is not fully supported by the description. Claim 1 recites a protein separation device comprising a chaperone protein immobilized on a substrate. However, the nature of the chaperone protein recited in claim 1 is not limited to the disclosure in the specification, mainly hsp60 or GroEL.
 - Similarly, claims 45-49 are not fully supported by the description.
- 2. Claim 32 is not clear. This claim is merely defined by result and not by any technical feature. It is not clear what form the GroEL must adopt to produce the desired results.
- 3. Claim 36 is not clear in scope and not fully supported by the description. It is not clear how the specificity is achieved or what the "particular protein' is. There is no substantial support in the description for such a broad claim.
- 4. Claim 43 is not clear in scope and not fully supported by the description. This claim has the features of claims 32 and 36 and comments in items 2-3 above therefore apply to this claim.
- 5. Claim 44 is not clear in scope and not fully supported by the description. This claim is merely defined by result and not by any technical feature. It is not clear what form the GroEL must adopt to produce the desired results. It is also not clear how the specificity is changed to that of another chaperone protein. There is no substantial support in the description for such a broad claim.